K033521

JAN 16 2004

Section 5
510 (k) SUMMARY

Applicant: Bisco, Inc.
1100 W. Irving Park Road
Schaumburg IL, 60193
Contact Person: Benjamin Lichtenwalner
Tel: 847-534-6146
Fax: 847-534-6111
Date Prepared: November 7, 2003

Trade Name: **BisBlock**
Common Name: Oxalate Dentin Desensitizing Agent
Classification/Name: Cavity Liner, Calcium Hydroxide
Class II per 21 CFR 872.3250

Description of Applicant Device:
BisBlock is an aqueous solution of oxalic acid in a semi-gel formulation. It is designed to be used on dentin etched with a phosphoric acid etchant prior to restoration of exposed dentin. It forms calcium oxalate crystals with dentin or bonds to the dentin. The crystals occlude the dentinal tubules opened with the etchant, which results in desensitization of natural dentition. The occlusion does not affect the following restoration.

Intended uses of Applicant Device:
BisBlock is a dentin desensitizing agent that is indicated for application prior to restoration of exposed dentin or when root surfaces are exposed. Its physical properties are similar to the predicate device and uses are identical.

Predicate Device: Super Seal from Phoenix Dental, Inc., cleared under K983477 dated 12/22/1998

Significant Performance Characteristics:

	BisBlock	Super Seal
Intended use	Dentin Desensitizer	Dentin Desensitizer
Chemical composite	Oxalate solution	Oxalate solution
Mechanical/physical properties	Blue semi-gel liquid that forms crystals (calcium oxalate) occluding dentinal tubules.	Clear low viscosity liquid that forms crystals (calcium oxalate) occluding dentinal tubules.

Side by side comparisons of **BisBlock** to the predicate device **Super Seal** from Phoenix Dental, Inc. clearly demonstrate that the applicant device is substantially equivalent to the legally marked devices. **BisBlock** was tested for biocompatibility and it was found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **BisBlock**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2004

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road,
Schaumburg, Illinois 60193

Re: K033521
Trade/Device Name: Bisblock
Regulation Number: 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: November 7, 2003
Received: November 10, 2003

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033521

Indications for Use

510(k) Number (if known): **K033521**

Device Name: **BisBlock**

Indications For Use:

BisBlock forms oxalate crystals which occlude the dentin tubules resulting in a reduction of sensitivity of teeth **by applying**:

1. Prior to temporization (placement of provisional restorations).
2. Prior to permanent cementation of indirect restorations.
3. Prior to placement of direct restorations.
4. When root surfaces are exposed.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K033521